



IFC

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): PAUL, Buddha D.	
Serial No.: 10,827,282	Group Art Unit: 1651
Filed: April 20, 2004	Examiner: Not Yet Assigned
Title: DETECTION OF OXIDIZING AGENTS IN URINE	
Attorney Docket No.: AFIP03-58 2	

Assistant Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

This Information Disclosure Statement is submitted:

- under 37 CFR 1.97(b), or  
(Within three months of filing national application; or date of entry of international application; or before mailing date of first office action on the merits; whichever occurs last)
- under 37 CFR 1.97(c) together with either a:
  - Certification under 37 CFR 1.97(e), or
  - a \$180.00 fee under 37 CFR 1.17(p), or  
(After the CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- under 37 CFR 1.97(d) together with a:
  - Certification under 37 CFR 1.97(e), and
  - a petition under 37 CFR 1.97(d)(2)(ii), and
  - a \$130.00 petition fee set forth in 37 CFR 1.17(i)(1).  
(Filed after final action or notice of allowance, whichever occurs first, but before payment of the issue fee)

**Certification under 37 CFR 1.97(e)(1)**

No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned, after making reasonable inquiry, was known to an

individual designated in 37 CFR 1.56 (e) more than three months prior to filing of the Information Disclosure Statement.

Applicant submit herewith Form PTO 1449-Information Disclosure Citation with copies of patents, publications or other information of which Applicant has become recently aware, that Applicant believes may be material to the examination of this application and for which there may be a duty to disclose in accordance with 37 CFR 1.56.

Neither this statement nor the listing of these documents on the accompanying form PTO-1449 should be considered as an admission by Applicant that these materials are prior art as to Applicant. In addition, this statement should not be construed as a representation that no better disclosures exist.

Entry of the Information Disclosure Statement and the accompanying Form PTO-1449 is respectfully solicited.

Respectfully submitted,

  
William E. Bradley, Reg. No. 42355  
CAHN & SAMUELS, LLP  
2000 P Street, N.W., Suite 200  
Washington, DC 20036  
Telephone: (202) 331-8777  
Facsimile: (202) 331-3838

July 20, 2004



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0851-0031

Approved for use through 10/20/2022. GPO:2019-090

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**Substitute for form 1449A/PTO**

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
*(use as many sheets as necessary)*

**(use as many sheets as necessary)**

Sheet

1

of

4

***Complete if Known***

<b>Application Number</b>	10,827,282
<b>Filing Date</b>	04/20/2004
<b>First Named Inventor</b>	PAUL, Buddha D.
<b>Art Unit</b>	1651
<b>Examiner Name</b>	Not Assigned
<b>Attorney Docket Number</b>	AFIP03-58 2

U.S. PATENT DOCUMENTS

## **FOREIGN PATENT DOCUMENTS**

<b>Examiner Signature</b>		<b>Date Considered</b>	
-------------------------------	--	----------------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04.

<sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST 3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449B/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				Application Number	10,827,282
				Filing Date	04/20/2004
				First Named Inventor	PAUL, Buddha D.
				Group Art Unit	1651
				Examiner Name	Not Assigned
Sheet	2	of	4	Attorney Docket Number	AFIP03-58 2

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	C	MIKKELSEN, et al., "Adulterants Causing False Negatives in Illicit Drug Testing," <i>Clinical Chemistry</i> , Vol. 34, No. 11, 1998, pp. 2333-2336.
	D	WARNER, Ann, "Interference of Common Household Chemicals in Immunoassay Methods for Drugs of Abuse," <i>Clinical Chemistry</i> , Vol. 35, No. 4, 1989, pp. 648-651.
	E	CODY, et al., "Impact of Adulterants on RIA Analysis of Urine for Drugs of Abuse," <i>Journal of Analytical Toxicology</i> , Vol. 13, September/October 1989, pp. 277-284.
	F	BRONNER, et al., "Detectability of Phencyclidine and 11-nor- $\Delta^9$ -Tetrahydrocannabinol-9-Carboxylic Acid in Adulterated Urine by Radioimmunoassay and Fluorescence Polarization Immunoassay," <i>Journal of Analytical Toxicology</i> , Vol. 14, November/December 1990, pp. 368-371.
	G	SCHWARZHOFF, et al., "The Effects of Adulterating Agents on FPIA Analysis of Urine for Drugs of Abuse," <i>Journal of Analytical Toxicology</i> , Vol. 17, January/February 1993, pp. 14-17.
	H	TSAI, et al., "Determination of Five Abused Drugs in Nitrite-Adulterated Urine by Immunoassays and Gas Chromatography-Mass Spectrometry," <i>Journal of Analytical Toxicology</i> , Vol. 22, October 1998, pp. 474-480.
	I	CODY, et al., "Effects of Stealth™ Adulterant on Immunoassay Testing for Drugs of Abuse," <i>Journal of Analytical Toxicology</i> , Vol. 25, September 2001, pp. 466-470.
	J	WU, et al., "Adulteration of Urine by 'Urine Luck'," <i>Clinical Chemistry</i> , Vo. 45, No. 7, 1999, pp. 1051-1057.
	K	BAIKER, et al., "Hypochlorite Adulteration of Urine Causing Decreased Concentration of $\Delta^9$ -THC-COOH by GC/MS," <i>Journal of Analytical Toxicology</i> , Vol. 18, March/April 1994, pp. 101-103.
	L	ELSOHLY, et al., "A Procedure to Overcome Interferences Caused by the Adulterant "Klear" in the GC-MS Analysis of 11-nor- $\Delta^9$ -THC-9-COOH," <i>Journal of Analytical Toxicology</i> , Vol. 21, May/June 1997, pp. 240-242.
	M	PAUL, et al., "Effects of Oxidizing Adulterants on Detection of 11-Nor- $\Delta^9$ -THC-9-Carboxylic Acid in Urine," <i>Journal of Analytical Toxicology</i> , Vol. 26, October 2002, pp. 460-463.

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449B/PTO				<b>Complete if Known</b>	
				Application Number	10,827,282
				Filing Date	04/20/2004
				First Named Inventor	PAUL, Buddha D.
				Group Art Unit	1651
				Examiner Name	Not Assigned
Sheet	3	of	4	Attorney Docket Number	AFIP03-58 2

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite, No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	N	Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Prevention, Division of Workplace Programs, "Guidance for Reporting Specimen Validity Testing," <i>National Laboratory Certification Program, Program Document 35</i> , September 28, 1998.
	O	Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Prevention, Division of Workplace Programs, "Specimen Validity Testing," <i>National Laboratory Certification Program, Program Document 37</i> , July 28, 1999.
	P	PAUL, et al., "Effects of Pyridinium Chlorochromate Adulterant (Urine Luck) on Testing Drugs of Abuse and a Method for Quantitative Detection of Chromium (VI) in Urine", <i>Journal of Analytical Toxicology</i> , Vol. 24, May/June 2000, pp. 233-237.
	Q	SINGH, et al., "The Measurement of Nitrite in Adulterated Urine Samples by High-Performance Ion Chromatography, <i>Journal of Analytical Toxicology</i> , Vol. 23, May/June 1999, pp. 137-140.
	R	FERSLEW, et al., "Capillary Ion Electrophoresis of Endogenous Anions and Anionic Adulterants in Human Urine," <i>Journal of Forensic Sciences</i> , Vol. 46, No. 3, 2001, pp. 615-626.
	S	CHILDS, et al., "The Steady-State Kinetics of Peroxidase with 2,2'-Azino-di-(3-ethyl-benzthiazoline-6-sulphonic acid) as Chromogen," <i>Biochemical Journal</i> , Vol. 145, 1975, pp. 93-103.
	T	VERMA, et al., "Excretion of Hydrogen Peroxide in Human Urine," <i>Free Radic. Res. Commun.</i> , Vol. 8, No. 2, 1990, pp-73-78 (abstract only).
	U	KUGE, et al., "Relation Between Natriuresis and Urinary Excretion of Hydrogen Peroxide," <i>Free. Radic. Res.</i> , Vol. 30, 1999, pp. 119-123.
	V	LONG, et al., "Hydrogen Peroxide in Human Urine: Implications for Antioxidant Defense and Redox Regulation," <i>Biochemical and Biophysical Research Communications</i> , Vol. 262, 1999, pp. 605-609.
	W	CRUICKSHANK, et al., "The Presence and Significance of Nitrites in Urine," <i>The British Medical Journal</i> , Vol. 2, 1914, pp. 712-713.
	X	Smith, et al., "Nitric Oxide Synthase: An Endogenous Source of Elevated Nitrite in Infected Urine," <i>Kidney International</i> , Vol. 45, 1994, pp. 586-591.

Examiner Signature	Date Considered
-----------------------	--------------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231

Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449B/PTO		<b><i>Complete if Known</i></b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>		<b>Application Number</b>	10,827,282
		<b>Filing Date</b>	04/20/2004
		<b>First Named Inventor</b>	PAUL, Buddha D.
		<b>Group Art Unit</b>	1651
		<b>Examiner Name</b>	Not Assigned
<b>Sheet</b>	4	<b>Attorney Docket Number</b>	AFIP03-58 2

#### **OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS**

<b>Examiner Signature</b>		<b>Date Considered</b>	
-------------------------------	--	----------------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231